GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2163
ANSWERED ON:05.03.2003
PERMISSION FOR NEW DRUGS
BALIRAM;P.R. KHUTE;S. SAIDUZZAMAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Authority for granting permission to new drugs lies only with the Drugs Controller General (India) and the State Drug Controllers;

(b) if so, whether many State Drug Controllers have been granting permission for new drugs in violation of the Drugs and Cosmetic Act and Rules;

(c) if so, the details of such violations by State Drug Controllers including the names of the companies and products; and

(d) the action taken/proposed to be taken against the erring authorities and companies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) The authority for granting permission for new drugs lies only with the Drugs Controller General (India).

(b) to (d) Some instances of issuing licences by State Licensing Authority for drugs which fall within the ambit of definition of new drug (Rule 122-E) have been noticed. Government has issued strict direction to all State Licensing Authorities to be careful in this regard.

Drugs & Cosmetics Rules 69, 71 and 75, which pertain to approval of drugs by State Licensing Authorities have also been amended vide Gazette Notification GSR 311 (E) dated 1st May, 2002 requiring that products falling within the purview of new drugs shall be accompanied with approval, in-writing, in favour of the applicant, from the office of DCG(I).